



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-10455 and CMS-R-290]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

ACTION: Notice.

SUMMARY: The Centers for Medicare & Medicaid Services (CMS) is announcing an opportunity for the public to comment on CMS' intention to collect information from the public. Under the Paperwork Reduction Act of 1995 (PRA), federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, and to allow a second opportunity for public comment on the notice. Interested persons are invited to send comments regarding the burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) the necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

DATES: Comments on the collection(s) of information must be received by the OMB desk officer by **[INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER]**:

ADDRESSES: When commenting on the proposed information collections, please reference the document identifier or OMB control number. To be assured consideration, comments and recommendations must be received by the OMB desk officer via one of the following transmissions:

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-5806 OR

E-mail: OIRA_submission@omb.eop.gov

To obtain copies of a supporting statement and any related forms for the proposed collection(s) summarized in this notice, you may make your request using one of following:

1. Access CMS' Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>.
2. E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov.
3. Call the Reports Clearance Office at (410) 786-1326.

FOR FURTHER INFORMATION CONTACT: Reports Clearance Office at (410) 786-1326.

SUPPLEMENTARY INFORMATION: Under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501-3520), federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. The term "collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide

information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires federal agencies to publish a 30-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension or reinstatement of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, CMS is publishing this notice that summarizes the following proposed collection(s) of information for public comment:

1. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Report of a Hospital Death Associated with Restraint or Seclusion; Use: Executive Order 13563, Improving Regulation and Regulatory Review, was signed on January 18, 2011. The order recognized the importance of a streamlined, effective, and efficient regulatory framework designed to promote economic growth, innovation, job creation, and competitiveness. Each agency was directed to establish an ongoing plan to reduce or eliminate burdensome, obsolete, or unnecessary regulations to create a more efficient and flexible structure.

The regulation that was published on May, 16, 2012 (77 FR 29034) included a reduction in the reporting requirement related to hospital deaths associated with the use of restraint or seclusion, §482.13(g). Hospitals are no longer required to report to CMS those deaths where there was no use of seclusion and the only restraint was 2-point soft wrist restraints. It is estimated that this will reduce the volume of reports that must be submitted by 90 percent for hospitals. In addition, the final rule replaced the previous requirement for reporting via telephone to CMS, which proved to be cumbersome for both CMS and hospitals, with a

requirement that allows submission of reports via telephone, facsimile or electronically, as determined by CMS. Finally, the amount of information that CMS needs for each death report in order for CMS to determine whether further on-site investigation is needed has been reduced.

The Child Health Act (CHA) of 2000 established in Title V, Part H, Section 591 of the Public Health Service Act (PHSA) minimum requirements concerning the use of restraints and seclusion in facilities that receive support with funds appropriated to any Federal department or agency. In addition, the CHA enacted Section 592 of the PHSA, which establishes minimum mandatory reporting requirements for deaths in such facilities associated with use of restraint or seclusion. Provisions implementing this statutory reporting requirement for hospitals participating in Medicare are found at 42 CFR 482.13(g), as revised in the final rule that published on May 16, 2012 (77 FR 29034). Form Number: CMS-10455 (OMB control number: 0938-1210); Frequency: Occasionally; Affected Public: Private Sector; Number of Respondents: 6,225; Number of Responses: 6,225; Total Annual Hours: 2,054. (For policy questions regarding this collection contact Karina Meushaw at 410-786-1000.)

2. Type of Information Collection Request: Extension of a currently approved collection; Title: Medicare Program: Procedures for Making National Coverage Decisions; Use: We revised our April 27, 1999 (64 FR 22619) notice and published a new notice on September 26, 2003 (68 FR 55634) that described the process we use to make Medicare coverage decisions including decisions regarding whether new technology and services can be covered. We have made changes to our internal procedures in response to the comments we received following publication of the 1999 notice and experience under our new process. Over the past several

years, we received numerous suggestions to further revise our process to continue to make it more open, responsive, and understandable to the public. We share the goal of increasing public participation in the development of Medicare coverage issues. This will assist us in obtaining the information we require to make a national coverage determination in a timely manner and ensuring that the Medicare program continues to meet the needs of its beneficiaries. Form Number: CMS-R-290 (OMB control number: 0938-0776); Frequency: Annual; Affected Public: Private Sector: Business or other for-profits; Number of Respondents: 200; Total Annual Responses: 200; Total Annual Hours: 8,000. (For policy questions regarding this collection contact Katherine Tillman at 410-786-9252.)

Dated: August 18, 2016

William N. Parham, III

Director, Paperwork Reduction Staff

Office of Strategic Operations and Regulatory Affairs

Billing Code: 4120-01-U-P

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